PSJ4 SOL Opp App A Exh 3

Review of Order Monitoring Program
Qualitest Pharmaceuticals
130 Vintage Drive
Huntsville, Alabama 35811

June 18, 2009

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Standard Operating Procedure:

The Standard Operating Procedure (SOP) for Qualitest Pharmaceuticals (QT) is SOP # QT01017.00. The SOP creates the policies by which controlled substances are distributed directly to retail pharmacies and practitioners by QT. The SOP created the Direct Retail Pharmacy Controlled Substance Questionnaire, the Retail Pharmacy Verification Checklist, the Retail Pharmacy Review, the Order Release Request, the Suspicious Order Report, the Practitioner Questionnaire, the Practitioner Verification Checklist, and the Practitioner Review.

Documents Reviewed:

The following documents were reviewed and appeared to be completed appropriately, leaving no questions for follow up:

- Three Practitioner Questionnaires and Three Practitioner Verification Checklist
- Ten Order Release Requests
- Forty Two Direct Retail Pharmacy Controlled Substance Questionnaire and Retail Pharmacy Verification Checklists

The following documents were reviewed and resulted in further questions:

- Five Practitioner Questionnaires and Practitioner Verifications
- Eighteen Direct Retail Pharmacy Controlled Substance Questionnaires and Retail Pharmacy Verification Checklists.
- Fourteen Order Release Requests

Each of the documents that required further explanations or had further questions was discussed with Jeremy Tatum, Inside Sales Manager for QT.

The following are examples of the questions that were raised while reviewing the documents:

1. A retail pharmacy in Kansas reported they ship to Kansas and Oklahoma but stated that they are not licensed in OK.
2. A retail pharmacy verification checklist for a pharmacy in North Plate, NE the verifier did not answer questions 3 and 4. A retail pharmacy in Breaux Bridge, LA is registered with an exempt DEA registration that is only for use at Federal or State institutions, as noted on the copy of the

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DEA 223 that was attached to the form. It is not known if the pharmacy has other DEA registrations.

3. A retail pharmacy in Seagoville, TX is shown on the TX Board of Pharmacy (BOP) web site as being on probation, but there was no follow up or issues noted on the Retail Pharmacy Verification Checklist.
4. Several pharmacies did not have pictures or copies of licenses or registrations attached, as requested.
5. A retail pharmacy in Moberly, MO is shown on the MO Division of Professional Registration website as on probation for numerous violations including controlled substance recordkeeping violations. This fact was not noted on the retail pharmacy verification checklist or shown as a response that suggests further inquiry.
6. There were several instances where retail pharmacies listed the names and DEA numbers of doctors that were prescribing narcotics in their area, but the names and DEA numbers were not checked because QT is not selling hydrocodone or oxycodone products directly to retail pharmacies.
7. For a retail pharmacy in New Iberia, LA the pharmacy did not answer several questions and that fact was noted on the Pharmacy Verification Checklist, but the checklist left blank the question about further inquiry.
8. For a retail pharmacy in Vidor, TX, there was information on the TX BOP website that both the pharmacy and pharmacist were on probation. The website did not provide additional information. The retail pharmacy verification checklist failed to mention the probation for the pharmacy and the pharmacist and did not highlight that as an issue for further inquiry.
9. A practitioner in Knoxville, TN was purchasing quantities of phentermine from QT. The phentermine was all being sent to a single location, then sent to the other four locations of the clinic by the purchaser. This distribution from one practitioner to another practitioner or location is a violation of 21 CFR 1307.11.
10. A physician in Oklahoma City, OK did not answer the question in the practitioner questionnaire about the quantities of controlled substances dispensed during a month. That fact was noted on the practitioner verification checklist, but no follow up was evident.
11. There was a weight management facility in Charleston, SC that has three other locations in the Southeast United Stated. The Practitioner Verification Checklist notes that all meds should be shipped to the Charleston, SC location, a violation of 21 CFR 1307.11.
12. A practitioner in Rosemead, CA failed to answer several questions on the practitioner questionnaire and put drug names as the answer to the questions about which suppliers you currently use and intent to continue to use. The verification checklist stated that all of the questions had been answered and there were no responses that would suggest further inquiry.
13. An order release form for a weight loss clinic in GA approved an increase in limits to 24,000 dosage units of phentermine a month. The form advised that the drugs will all be shipped to a single location for the other three locations, a violation of 21 CFR 1307.11.

There were several order release request forms that were not completed with the requested information. The reason given for the increase in limit was simply for additional business. There

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may have been additional reasons, but the reasons were not documented on the order release forms.

Suspicious Order reporting to DEA:

All orders that are identified by Qualitest as suspicious require the completion of a QT01017.05, Suspicious Order Report. The report is filed in the office of the Qualitest Director of Compliance and faxed to the DEA Diversion Group Supervisor in the DEA office in Birmingham, Alabama.

The most recent suspicious order report was forwarded to DEA on October 7, 2008 and concerned a pharmacy in Houston, TX that ordered suspicious quantities of hydrocodone. This suspicious order was well documented with a letter to DEA and the fax confirmation sheet that shows the date and time that the document was transmitted to the DEA office in Birmingham, AL.

The review of Order Release Requests showed that many requests were made for quantities of drugs that were several times greater than the current limit set in the order monitoring system. In most of those instances, the size of the order was cut down and the order was approved to be released, with some increase to the limit in the Order Monitoring System. Although the original order requested a quantity of controlled substances that was larger than QT was willing to ship to the customer, no report of a suspicious order was sent to the DEA as required by 21 CFR 1301.74(b). Each Order Release Request that is rejected or modified by QT should be sent to DEA as a suspicious order. Sending these orders to DEA will document to DEA that QT is monitoring the orders on a continuing basis and is monitoring controlled substance orders in a reasonable manner.

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SUGGESTED CHANGES TO THE SOP:¶
QUALITEST PHARMACEUTICALS¶
130 Vintage Drive¶
Huntsville, AL 35811¶
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STANDARD OPERATING PROCEDURE¶
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CONTROLLED INVENTORY ORDERS REV 07
PAGE 1 OF 4 ¶
SOP#: QT01017.00¶
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TITLE: EXCESSIVE AND SUSPICIOUS ORDER REVIEW AND MAINTENANCE¶
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WRITTEN BY/DATE:
_____¶
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APPROVED BY/DATE:
_____¶
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INITIATOR: _____EFFECTIVE DATE: _____¶
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PURPOSE: To define the procedure for reviewing orders which contain suspicious or excessive quantities of controlled substances and the reporting of the suspicious orders to the Drug Enforcement Administration (DEA).¶
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SCOPE: This procedure applies to customer service representatives and outside sales representatives who prepare controlled substance customer orders for both new and established accounts.¶
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DEFINITIONS: N/A¶
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PROCEDURE:¶
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REVIEW OF NEW ACCOUNT INITIAL ORDERS¶
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The appropriate customer service representatives/sales representatives preparing to service new accounts ... [1]

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SUGGESTED CHANGES TO THE SOP:
QUALITEST PHARMACEUTICALS
130 Vintage Drive
Huntsville, AL 35811

STANDARD OPERATING PROCEDURE

CONTROLLED INVENTORY ORDERS REV 07 PAGE 1 OF 4
SOP#: QT01017.00

TITLE: EXCESSIVE AND SUSPICIOUS ORDER REVIEW AND MAINTENANCE

WRITTEN BY/DATE: _____

APPROVED BY/DATE: _____

INITIATOR: _____EFFECTIVE DATE: _____

PURPOSE: To define the procedure for reviewing orders which contain suspicious or excessive quantities of controlled substances and the reporting of the suspicious orders to the Drug Enforcement Administration (DEA).

SCOPE: This procedure applies to customer service representatives and outside sales representatives who prepare controlled substance customer orders for both new and established accounts.

DEFINITIONS: N/A

PROCEDURE:

REVIEW OF NEW ACCOUNT INITIAL ORDERS

The appropriate customer service representatives/sales representatives preparing to service new accounts requesting delivery of controlled substances shall complete the Direct Retail Pharmacy Controlled Substance Questionnaire (Form No. QT01017.01) and/or Practitioner Questionnaire (Form No. QT01017.06), Retail Pharmacy Verification Checklist (Form No. QT01017.02) and/or Practitioner Verification Checklist (Form No. QT01017.07) prior to printing the new customer's initial order.

A copy of the customer's current DEA registration certificate or a print out of the DEA website registrant profile shall be attached to the new customer initial order printout.

The new account's location shall be verified by the Pharmacy Permit from the account's relevant State Board of Pharmacy or physician's license from the State Board of Medical Examiners.

Once the new account information is complete, their DEA registration and location have been verified the appropriate customer service representative shall attach the required documentation to the printout of the initial order.

The Sales Manager shall approve new retail customers and their initial order containing controlled substances. The Vice President of Sales and/or the Vice President of National Accounts shall approve the new non-retail customers and their initial orders containing controlled substances.

Qualitest will not sell only hydrocodone/oxycodone to a new retail pharmacy customer or new physician's practice or clinic.

The approved initial order shall then be released for inventory picking and shipping.

The required documents completed in "A." of this section shall be maintained in both electronic (Computer) and hard copy individual customer files.

Initial orders that are not approved by the appropriate manager shall be flagged as suspicious or excessive. The inside Sales Manager/designee shall then alert the Qualitest Department Manager and DEA Compliance for determination of notification to the DEA.

The DEA shall be notified upon determination of suspicious order using Suspicious Order Report (Form # QT01017.05). Additional written follow-up shall be sent to DEA as deemed appropriate.

New customers shall be subject to this new account review every thirty (30) days for the first ninety (90) days.

REVIEW OF ESTABLISHED ACCOUNT ORDERS

After an initial order for a customer account has been shipped the customer may be considered an established account.

Orders exceeding 3,000 combined doses of any strength of Hydrocodone solid dose products; 1,000 combined doses of Oxycodone; 3,000 doses of Phentermine; 3,000 doses of

Alprazolam; 6,000 doses of Diazepam; 6,000 doses of Clonazepam; 12,000 doses of Carisoprodol; or 12,000 doses of Propoxyphene, either as a single order, or multiple orders within a thirty-one calendar day rolling period, shall be stopped from processing due to electronic order entry modifications. These orders shall be flagged, and must be manually reviewed and approved by the Sales Manager/designee or Qualitest Department Manager prior to release for shipment. An Order Release Request (Form No. QT01017.04) shall be completed and signed by appropriate management.

In addition a report shall be generated and reviewed by a customer service supervisor on a bi-weekly basis for all established retail accounts, to see if any such account has ordered more than 3,000 combined doses of Hydrocodone; 1,000 combined doses of Oxycodone ; 3,000 combined doses of Phentermine; 3,000 combined doses of Alprazolam; 6,000 combined doses of Diazepam; 6,000 combined doses of Clonazepam; 12,000 combined doses of Carisoprodol; or 12,000 combined doses of Propoxyphene within a thirty-one calendar day rolling period. A Retail Pharmacy Review Checklist (Form No. QT01017.03) and/or a Practitioner Review Checklist (Form No.QT01017.08) will be completed quarterly and additional reporting may be created to track other controlled substances for established accounts, if deemed necessary, to assist customer service representatives in the review of excessive and suspicious orders.

Any established account orders containing additional controlled substances (other than Hydrocodone, Phentermine, Carisoprodol, Alprazolam, Clonazepam and/or Propoxyphene) may also be flagged as suspicious or excessive by a customer service representative and shall be reviewed manually and agreed to by the Sales Manager or Qualitest Department Manager prior to processing.

Orders for established customer accounts that are not approved by the Sales Manager or Qualitest Department Manager shall be flagged as suspicious or excessive. The customer service department shall then alert Qualitest Department management and DEA Compliance.

Qualitest Department management and DEA compliance shall make a determination if the DEA should be contacted concerning any potential suspicious order.

The DEA shall be notified upon determination of suspicious order using Suspicious Order Report (Form # QT01017.05). Additional written follow-up shall be sent to DEA as deemed appropriate.

Qualitest Department Management, after due diligence, may modify the quantity limits and / or time periods for the automatic hold and review of specific individual retail customers.

Existing customers that have not made any scheduled drug purchases for six (6) consecutive months shall be subject to the review required for new accounts when placing a scheduled drug order.

END SOP REV07 10/08

REVISION HISTORY:

Revision 00- Creation of a new SOP
Revision 01- The Excessive and Suspicious Order Review SOP was rewritten to account for new procedures that have been put in place.
Revisions 02-The products, Carisoprodol and Propoxyphene Napsylate have been added to sections II., B., C., and D.
Revision 03- Section I., I. was added. Section II., G. was added.

Revision 04- Revision Section I., E. - The official titles of management were added as employees who may approve new customers and initial orders with controlled substances. Section I., F. was added.
Revision 05- The products, Diazepam and Clonazepam have been added to sections II., B., C., and D.
Revision 06- Oxycodone added for suspicious order monitoring, outside sales reps added for suspicious order monitoring, Forms QT01017.01 – QT01017.05 added.
Revision 07- Alprazolam has been added to sections II., B.,C., and D. Forms QT01017.06-QT 01017.08 added.